Quality Manual
SOP 100

Revision 9

Issued April 6, 2022

Conforms to ISO 9001:2015

Table of Contents

1.0 Approval and Revision History

Authorized By: **Date:**

Patricia Facchini 4/6/22

Patricia Facchini, Managing Director

BiosPacific, Inc., Bio-Techne Diag Div Emeryville

Revision History:

Rev.	Description of changes	Date
9	Revise Organization chart and minor typos	See above
8	Rewrite; Updated general format and included additional sections to better comply with ISO 9001:2015.	See above
0 to 7	Refer to hard copies	Refer to hard copies

2.0 About the BiosPacific Quality Manual

This manual describes the Quality System at BiosPacific and is considered the top tier of our documentation system. The organizational structure, responsibilities, procedures, processes and resources for implementing quality management are described. Related Standard Operating Procedures (SOPs) are referenced where applicable.

3.0 Terms and Definitions

BiosPacific adopts the following terms and definitions within its Quality Management System. Where no definition is provided, the company typically adopts the definitions provided in *ISO 9000: Quality Management – Fundamentals and Vocabulary.* In some cases, specific procedures or documentation may provide a different definition to be used in the context of that document; in such cases, the definition will supersede those provided for in this Quality Manual or ISO 9000.

General Terminology

BiosPacific – BiosPacific, Inc.

SOP - Standard Operating Procedure. Written information used to describe how an activity is done.

Record - captured evidence of an activity having been done.

Risk-Based Thinking Terminology

Risk – Negative effect of uncertainty

Opportunity – Positive effect of uncertainty

Uncertainty - A deficiency of information related to understanding or knowledge of an event, its consequence, or likelihood. (Not to be confused with measurement uncertainty.)

Nonconforming Product Terminology

Rework: Efforts to bring nonconforming product into conformance through additional operations that *do not* alter the original design of the product.

Scrap: The discard of nonconforming product in lieu of rework or repair.

4.0 Context of the Organization

BiosPacific has been a distributor of proteins and antibodies for manufacturers for over 30 years. BiosPacific is experienced in meeting the rigorous demands of the industrial client. The success of BiosPacific has been due, in large part, to commitment to find the most effective solutions for the needs of the In Vitro Diagnostic and research industries. An expansive range of monoclonal antibodies, affinity purified polyclonal antibodies and purified proteins for immunoassay development allow for world class support and collaboration with customers from feasibility to manufacturing. The staff is primarily sales and sales support, and works closely with customers and product vendors to assure that the customer's requirements are met. The office is located in Emeryville, California.

In July 2005, BiosPacific was purchased by R&D Systems, Inc. (R&D Systems) and became a wholly owned subsidiary. R&D Systems was founded in 1976 in Minneapolis, MN. It is a wholly owned subsidiary of TECHNE Corporation (a holding company with no employees). In July 2014, TECHNE was renamed as Bio-Techne. The stock is traded publicly on NASDAQ's National Market System under the "TECH" symbol.

Regulatory oversight is provided by sites within Bio-Techne Corporation based on customer and product information supplied by BiosPacific. Areas where regulatory support is available are audits, training, ISO

certification, labeling, import/export regulations, reporting hazardous materials, and other applicable regulations as necessary.

4.1 Understanding the Organization and Its Context

BiosPacific has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the company. This requires understanding internal and external issues that are of concern to BiosPacific and its interested parties (per 4.2 below); the interested parties are identified per the document, Interested Parties List.

Such issues are monitored and updated as appropriate, and discussed as part of management reviews.

4.2 Understanding the Needs and Expectations of Interested Parties

The issues determined per 4.1 above are identified through an analysis of risks facing BiosPacific and its interested parties. "Interested parties" are those stakeholders who receive our products or services, or who may be impacted by them, or those parties who may otherwise have a significant interest in our company. These parties are identified per the document, Interested Parties List.

This information is then used by senior management to determine the company's strategic direction. This is defined in records of management review, and periodically updated as conditions and situations change.

4.3 Determining the Scope of the Quality Management System

Based on an analysis of the above issues of concern, interests of stakeholders, and in consideration of its products and services, BiosPacific has determined the scope of the management system as follows:

Supply and distribution of immunological reagents, highly purified monoclonal and polyclonal antibodies, native and recombinant proteins.

The quality system applies to all processes, activities and employees within the company. The facility is located at:

5980 Horton Street #360
Emeryville, CA 94608

Phone: 510-652-6155
Fax: 510-652-4531

Web: www.biospacific.com

The following clauses of ISO 9001 were determined to be not applicable to BiosPacific.

- Section 8.3 Design and Development of Products and Services (BiosPacific does not perform design and development activities)

Applicable Standards: EC No 1069/2009 and EU 142/2011, ISO 9001:2015

BiosPacific has been ISO certified since 8/26/2011. Certificate of Registration is # 19.8268.

4.4 Quality Management System and Its Processes

4.4.1 Process Identification

BiosPacific has adopted a process approach for its management system. By identifying the top-level processes within the company, and then managing each of these discretely, this reduces the potential for nonconforming products discovered during final processes or after delivery. Instead, nonconformities and risks are identified in real time, by actions taken within each of the top-level processes.

The following top-level processes have been identified for BiosPacific:

- Sales, Customer Service and Contract Review
- Purchasing and Supplier Management
- Re-labeling and Aliquoting
- Storage, Logistics and Delivery

Each process may be supported by other activities, such as tasks or sub-processes. Monitoring and control of top-level processes ensures effective implementation and control of all subordinate tasks or sub-processes.

The sequence of interaction of these processes is illustrated in Appendix A.

4.4.2 Outsourced Processes

Any process performed by a third party is considered an "outsourced process" and must be controlled, as well. The company's outsourced processes, and the control methods implemented for each, are defined in process specific SOP's.

The type and extent of control to be applied to the outsourced process take into consideration:

a) the potential impact of the outsourced process on the company's capability to provide product that conforms to requirements,

b) the degree to which the control for the process is shared,

c) the capability of achieving the necessary control through the purchasing contract requirements.

Related Procedure:	SOP 400	Equipment Maintenance and Calibration
	SOP 401	Computer Maintenance

5.0 Leadership

5.1 Leadership & Commitment

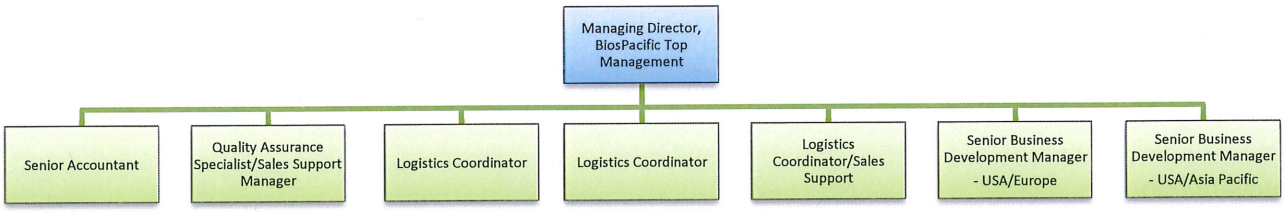
5.1.1 General

The top management at Biospacific demonstrate leadership and commitment to the Quality Management System. This includes the following responsibilities:

- works with Quality Assurance and Regulatory Affairs within Bio-Techne to assure that the quality system at BiosPacific is adequately planned for, established and effective and achieves its intended result;

- provides input regarding the performance of the quality system at BiosPacific, establishes and communicates the Quality Objectives, and evaluates performance to the Objectives via Management Review;
- develops the Quality Policy ensuring it is in line with the company's strategic direction; communicates and ensures the Quality Policy is understood; reviews the Policy periodically;
- works with Quality Assurance and Regulatory Affairs within Bio-Techne to assess risks and opportunities that will enhance desirable effects and reduce or prevent undesired effects while striving to improve the Quality Management System. Consideration is given to the potential impact on the conformity of products and services;
- promotes awareness of the process approach;
- ensures resources are adequately available;
- communicates the importance of conformance to the quality system; reviews and monitors the effectiveness of the quality system in an annual Management Review to assess/verify effectiveness and adequacy of actions taken to implement improvement opportunities;
- promotes awareness of customer requirements;
- promotes continual improvement;
- ensures integrity of the Quality Management System when changes are planned and implemented.

5.1.1.1 Organizational Chart



5.1.2 Customer focus

The top management of BiosPacific adopts a customer-first approach which ensures that customer needs and expectations are determined, converted into requirements and are met with the aim of enhancing customer satisfaction.

This is accomplished by assuring:

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;

b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

c) the focus on enhancing customer satisfaction is maintained.

5.2 Policy

The top management of BiosPacific has developed the Quality Policy that governs day-to-day operations to ensure quality. The Quality Policy is released as a standalone document as well and is communicated and implemented throughout the organization.

The Quality Policy of BiosPacific is as follows:

BiosPacific, Inc. is committed to the highest level of quality in the distribution, sales and support of the products we sell and will maintain and continually improve the effectiveness of our Quality Management System. Product quality, compliance to all applicable regulatory requirements and standards, continuous improvement and customer satisfaction shall underlie all of our efforts in the distribution, advertising, sales, shipping and technical support of our products.

5.3 Organizational Roles Responsibilities and Authorities

BiosPacific management has assigned responsibilities and authorities for all relevant roles in the company. These are communicated through the combination of the Organizational Chart and the Managing Director.

In addition, the following overall QMS responsibilities and authorities are assigned as follows:

Responsibility	Assigned To
Ensuring that the management system conforms to applicable standards	Managing Director and Quality Representative
Ensuring that the processes are delivering their intended outputs	Operational employees
Reporting on the performance of the management system and providing opportunities for improvement for the management system	Managing Director
Ensuring the promotion of customer focus throughout the organization	Top Management
Ensuring that the integrity of the management system is maintained when changes are planned and implemented	Top Management and Quality Representative

Related Procedure: SOP 209 Management Review of the Quality System

6.0 Planning

6.1 Actions to Address Risks and Opportunities

BiosPacific considers risks and opportunities when taking actions within the management system, as well as when implementing or improving the management system; likewise, these are considered relative to products and services.

A list of potential risks and their respective mitigations can be found in Appendix B.

6.2 Quality Objectives and Planning to Achieve Them

As part of the adoption of the process approach, BiosPacific utilizes its process objectives, as discussed in 4.4 above, as the main quality objectives for the QMS. These include overall product-related quality objectives; additional product-related quality objectives may be defined in work instructions or customer requirements.

The process objectives have been developed in consideration that they:

a) be consistent with the quality policy;

b) be measurable;

c) take into account applicable requirements;

d) be relevant to conformity of products and services and to enhancement of customer satisfaction;

e) be monitored;

f) be communicated;

g) be updated as appropriate.

Process quality objectives are defined in the minutes of management review per section 9.3 below.

The planning of process quality objectives is defined in section 4.4. above.

6.3 Planning of Changes

Changes to the quality management system and its processes are carried out in a planned manner per the Management Review procedure.

Related Procedure: SOP 209 Management Review of the Quality System

7.0 Support

7.1 Resources

7.1.1 General

BiosPacific determines and provides the resources needed:

a) to implement and maintain the management system and continually improve its effectiveness

b) to enhance customer satisfaction by meeting customer requirements

Resource allocation is done with consideration of the capability and constraints on existing internal resources, as well as needs related to supplier expectations.

Resources and resource allocation are assessed during management reviews.

7.1.2 People

Top management ensures that it provides sufficient staffing for the effective operation of the management system, as well its identified processes.

7.1.3 Infrastructure

BiosPacific determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

a) buildings, workspace and associated facilities;

b) process equipment, hardware and software;

c) supporting services such as transport;

d) information and communication technology.

7.1.4 Environment for the Operation of Processes

BiosPacific provides a clean, safe and well-lit working environment. The Management of BiosPacific manages the work environment needed to achieve conformity to product requirements. Specific environmental requirements for products are determined during quality planning and are documented in subordinate procedures, work instructions, or job documentation. Where special work environments have been implemented, these shall also be maintained per 6.3 above. Human factors are considered to the extent that they directly impact on the quality of products or services.

7.1.5 Monitoring and Measuring Resources

Where equipment is used for critical measurement activities, such as bottling and labeling, these shall be subject to control and either calibration or verification;

Related Procedure: SOP 400 Equipment Maintenance and Calibration

7.1.6 Organizational Knowledge

BiosPacific also determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This may include knowledge and information obtained from:

a) internal sources, such as lessons learned, feedback from subject matter experts, and/or intellectual property;

b) external sources such as standards, academia, conferences, and/or information gathered from customers or suppliers.

This knowledge shall be maintained and made available to the extent necessary.

When addressing changing needs and trends, BiosPacific shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge.

7.2 Competence

Staff members performing work affecting product quality are competent on the basis of appropriate education,

training, skills and experience. The documented procedure defines these activities in detail. Employees are also trained to corporate policies via the Bio-Techne Academy/Compliance Wire.

Related Procedure: SOP 201 Personnel Training

7.3 Awareness

Training and subsequent communication ensure that staff are aware of:

a) the quality policy;

b) relevant quality objectives;

c) their contribution to the effectiveness of the management system, including the benefits of improved performance;

d) the implications of not conforming with the management system requirements.

7.4 Communication

The top management of BiosPacific ensures internal communication takes place regarding the effectiveness of the management system. Internal communication methods typically include:

a) use of corrective and preventive action processes to report nonconformities or suggestions for improvement

b) use of the results of analysis of data

c) meetings (periodic, scheduled and/or unscheduled) to discuss aspects of the QMS

d) use of the results of the internal audit process

e) regular company meetings with all employees

f) internal emails

7.5 Documented Information

The management system documentation includes both documents and records.

The extent of the management system documentation has been developed based on the following:

a) The size of BiosPacific

b) Complexity and interaction of the processes

c) Risks and opportunities

d) Competence of personnel

Documents required for the management system are controlled in accordance with the Document Control procedure. The purpose of document control is to ensure that staff have access to the latest, approved information, and to restrict the use of obsolete information. All documented procedures are established, documented, implemented and maintained.

Documented procedures have been established to define the controls needed for the identification, storage, retrieval, protection, retention time, and disposition of quality records. This procedure also defines the methods for controlling records that are created by and/or retained by suppliers.

These controls are applicable to those records which provide evidence of conformance to requirements; this may be evidence of [Product or Service Sing.] requirements, contractual requirements, procedural requirements, or statutory/regulatory compliance. In addition, quality records include any records which provide evidence of the effective operation of the management system.

Related Procedure: SOP 200 Document Control
SOP 211 Control of Records
SOP 400 Equipment Maintenance and Calibration

8.0 Operation

8.1 Operational Planning and Control

BiosPacific plans and develops the processes needed for realization of its products and services. Planning of product realization is consistent with the requirements of the other processes of the management system. Such planning considers the information related to the context of the organization (see section 2.0 above), current resources and capabilities, as well as product and customer requirements.

Such planning is accomplished through:

a) determining the requirements for the products;

b) establishing criteria for the processes and the acceptance of;

c) determining the resources needed to achieve conformity to the requirements;

d) implementing control of the processes in accordance with the criteria;

e) determining, maintaining and retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate the conformity of product to their requirements.

Changes to operational processes are done in accordance with the Document Control SOP.

Outsourced processes and the means by which BiosPacific controls them are defined in the Vendor Qualification procedure.

Related Procedure: SOP 200 Document Control
SOP 207 Vendor Qualification

8.2 Requirements for Products and Services

8.2.1 Customer Communication

BiosPacific has implemented effective communication with customers in relation to:

a) providing information relating to products;

b) handling enquiries, contracts or orders, including changes;

c) obtaining customer feedback relating to products and services, including customer complaints;

d) handling or controlling customer property;

e) establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the Requirements Related to Products and Services

During the intake of new business BiosPacific captures:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;

b) requirements not stated by the customer but necessary for specified or intended use, where known

c) statutory and regulatory requirements related to products;

d) any additional requirements determined by BiosPacific.

These activities are defined in greater detail in the Contracts and Supply Agreements and Order Processing procedures.

Related Procedure: SOP 300 Contracts and Supply Agreements
SOP 301 Order Processing

8.2.3 Review of Requirements Related to Products and Services

Once requirements are captured, BiosPacific reviews the requirements prior to its commitment to supply the product. This review ensures that BiosPacific has the capability and capacity to:

a) meet all requirements specified by the customer, including requirements for delivery and post-delivery activities;

b) meet any requirements not stated by the customer, but which BiosPacific knows as being necessary;

c) meet all requirements determined necessary by BiosPacific itself;

d) meet all related statutory and regulatory requirements;

e) meet any contract or order requirements differing from those previously expressed (i.e., from a previous BiosPacific quote).

These activities are defined in greater detail in the below procedures:

Related Procedure: SOP 300 Contracts and Supply Agreements
SOP 301 Order Processing
SOP 308 Supply Specs and Order Form

8.2.4 Changes to Requirements for Products and Services

BiosPacific updates all relevant requirements and documents when the requirements are changed, and ensures that all appropriate staff are notified; these changes are typically documented in the following procedures:

Related Procedure: SOP 200 Document Control
SOP 300 Contracts and Supply Agreements
SOP 308 Supply Specs and Order Form

8.3 Control of Externally Provided Processes, Products and Services

BiosPacific ensures that purchased products conform to specified purchase requirements. The type and extent of control applied to the supplier and the purchased products or services are dependent on the effect on subsequent product realization or the final product.

BiosPacific evaluates and selects suppliers based on their ability to supply products and services in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation are established.

Purchases are made via the release of formal purchase orders and/or contracts which clearly describe what is being purchased. Received products or services are then verified against requirements to ensure satisfaction of requirements. Suppliers who do not provide conforming products or services may be requested to conduct formal corrective action.

These activities are further defined in documents.

Related Procedure:
SOP 301 Order Processing
SOP 300 Contracts and Supply Agreements
SOP 308 Supply Specs and Order Form

8.4 Production and Service Provision

8.4.1 Control of Production and Service Provision

To control its provision of products or services, BiosPacific considers, as applicable, the following:

a) the availability of documents or records that define the characteristics of the products as well as the results to be achieved;

b) the availability and use of suitable monitoring and measuring resources;

c) the implementation of monitoring and measurement activities;

d) the use of suitable infrastructure and environment;

e) the appointment of competent persons, including any required qualifications;

f) the validation and revalidation of special processes if applicable (see below);

g) the implementation of actions to prevent human error;

h) the implementation of release, delivery and post-delivery activities.

8.4.2 Identification and Traceability

Where appropriate, BiosPacific identifies its product or other critical process outputs by suitable means. Such identification includes the status of the product with respect to monitoring and measurement requirements. Unless otherwise indicated as nonconforming, pending inspection or disposition, or some other similar identifier, all product shall be considered conforming and suitable for use.

If unique traceability is required by contract, regulatory, or other established requirement, BiosPacific controls and records the unique identification of the product.

Documented procedures define these methods in detail.

Related Procedure:
SOP 205 Recordkeeping
SOP 302 Receiving
SOP 304 Bottling and Labeling

8.4.3 Property Belonging to Customers or External Providers

BiosPacific exercises care with customer or supplier property while it is under the organization's control or being used by the organization. Upon receipt, such property is identified, verified, protected and safeguarded. If any such property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer or supplier and records maintained.

For customer intellectual property, including customer furnished data used for design, production and / or inspection, this is identified by customer and maintained and preserved to prevent accidental loss, damage or inappropriate use.

Related Procedure: SOP 210 Control of Customer Property

8.4.4 Preservation

BiosPacific preserves conformity of product or other process outputs during internal processing and delivery. This preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product.

Documented procedures define the methods for preservation of product.

Related Procedure: SOP 302 Receiving
SOP 304 Bottling and Labeling
SOP 305 Shipping Procedure

8.4.5 Post-Delivery Activities

As applicable, BiosPacific conducts the following activities which are considered "post-delivery activities":

- Invoicing
- Customer complaint handling
- Customer satisfaction
- Field notifications

Post-delivery activities are conducted in compliance with the management system defined herein. In determining the extent of post-delivery activities that are required, BiosPacific considers:

a) statutory and regulatory requirements;

b) the potential undesired consequences associated with its products;

c) the nature, use and intended lifetime of its of products;

d) customer requirements;

e) customer feedback.

Related Procedure: SOP 202 Complaint Handling
SOP 206 Field Notifications
SOP 208 Customer Satisfaction
SOP 306 Invoice Entry

8.4.6 Control of Changes

BiosPacific reviews and controls both planned and unplanned changes to processes to the extent necessary to ensure continuing conformity with all requirements.

Process change management is defined.

Documents are changed in accordance with established procedure.

Related Procedure:
SOP 200 Document Control
SOP 203 Corrective and Preventive Action
SOP 209 Management Review

8.5 Release of Products

Acceptance criteria for products are defined in appropriate subordinate documentation. Reviews and inspections are conducted at appropriate stages to verify that the requirements have been met. This is done before products are released or services are delivered.

Each process utilizes different methods for measuring and/or aliquoting and releasing products. These methods are defined in established procedures.

Related Procedure:
SOP 302 Receiving
SOP 304 Bottling and Labeling
SOP 305 Shipping Procedure

8.6 Control of Nonconforming Outputs

BiosPacific ensures that products or other process outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The controls for such nonconformances are defined in an established procedure.

Related Procedure: SOP 309 Non-conforming Product

9.0 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

BiosPacific has determined which aspects of its quality management system must be monitored and measured, as well as the methods to utilize and records to maintain, within this Quality Manual and subordinate documentation.

Monitoring and measurement of the processes, as defined in 4.4 above, ensure that the Top Management evaluates the performance and effectiveness of the quality management system itself.

9.1.2 Customer Satisfaction

As one of the measurements of the performance of the management system, BiosPacific monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information include:

- recording customer complaints
- product rejections or returns
- changing volume of orders for product
- trends in on-time delivery
- obtain customer scorecards from certain customers
- submittal of customer satisfaction surveys

The corrective and preventive action system shall be used to develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations and assess the effectiveness of the results.

Related Procedure: SOP 202 Complaint Handling
SOP 203 Corrective and Preventive Action
SOP 208 Customer Satisfaction
SOP 209 Management Review

9.1.3 Analysis and Evaluation

BiosPacific analyzes and evaluates the data and information arising from monitoring and measurement in order to evaluate:

a) conformity of product;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the quality management system;
d) if planning has been implemented effectively;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) the need for improvements to the quality management system.

Statistical techniques used may be defined in appropriate documented procedures; in all cases, the methods are based on established standards or are otherwise determined to be statistically valid.

Related Procedure: SOP 209 Management Review

9.2 Internal Audit

BiosPacific conducts internal audits at planned intervals to determine whether the management system conforms to contractual and regulatory requirements, to the requirements of ISO 9001, and to management system requirements. Audits also seek to ensure that the management system has been effectively implemented and is maintained.

These activities are defined in an established procedure.

Related Procedure: SOP 502 Internal Audits

9.3 Management Review

The Top Management reviews the management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The review includes assessing opportunities for improvement, and the need for changes to the management system, including the ***Quality Policy*** and quality objectives.

Management review frequency, agenda (inputs), outputs, required members, actions taken, and other review requirements are defined in the documented procedure

Records from management reviews are maintained.

Related Procedure: SOP 209 Management Review

10.0 Improvement

10.1 General

BiosPacific uses the management system to improve its processes, products and services. Such improvements aim to address the needs and expectations of customers as well as other interested parties, to the extent possible.

Improvement shall be driven by an analysis of data related to:

The results of analysis shall be used to evaluate:

h) conformity of products and services;

i) the degree of customer satisfaction;

j) the performance and effectiveness of the management system;

k) the effectiveness of planning;

l) the effectiveness of actions taken to address risks and opportunities;

m) the performance of external providers;

n) other improvements to the management system.

10.2 Nonconformity and Corrective Action

BiosPacific takes corrective action to eliminate the cause of nonconformity in order to prevent recurrence. Likewise, the company takes preventive action to eliminate the causes of potential nonconformities in order to prevent their occurrence.

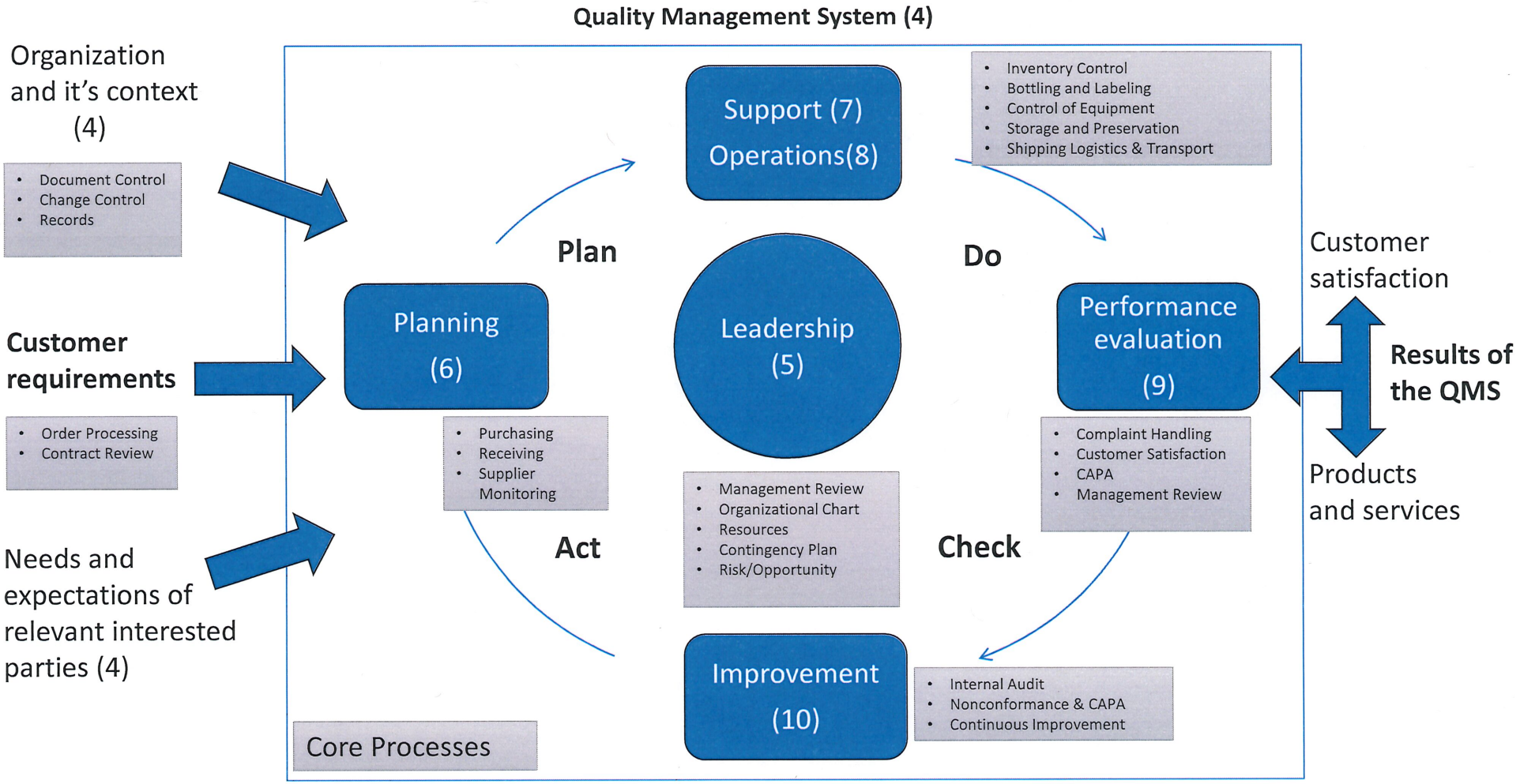
These activities are done through the use of the formal Corrective Action system and are defined in an established document.

Related Procedure: SOP 203 Corrective and Preventive Action
SOP 309 Non-conforming Product

10.3 Continual Improvement

Through the process effectiveness reviews, done as part of Management Review, BiosPacific works to continually improve the suitability, adequacy and effectiveness of the quality management system. This includes seeking opportunities for improvement.

SOP 100 Appendix A
Overall Process Sequence & Interaction



SOP 100 Appendix B

BiosPacific Risk and Mitigation Register

Core Processes Section	Process	Process Element	Potential Risk	Mitigation or Control in Place	Indicators or Areas to Review	Opportunities
7	**Records**	Traceability	Loss of documented evidence	All records are filed by year. Records are transferred to bankers boxes at 3 years. Most key information is retained in SAGE and can be recovered. The manufacturers CofA/Data Sheets are scanned.	Management Review Minutes	Scan additional documents that cannot obtained from SAGE
		Traceability	Damage to documented evidence (fire, water)	same as above	same as above	same as above
7	**Control of Equipment**	Calibration	Out of calibration	Pipettes calibrated by Eppendorf. Thermometers are calibrated by Senscoscientific.	Internal, customer, and regulatory audits	
		Calibration	Availability of calibrated equipment	Three sets of pipettes are kept inhouse	SOP	
8	**Order Processing**	Information for External Providers	Inaccurate order entry (SAGE)	The customer PO is verified against what has been entered into SAGE.	Complaints	
8	**Purchasing**	same as above	same as above	same as above	Complaints	
8	**Receiving**	Control of externally provided product	Wrong product sent by supplier	The PO given to the supplier is verified against the sales order (SAGE) at the time of receiving.	Complaints	
8	**Supplier Monitoring**	Supplier performance	Poor product on market	Suppliers are qualified initially and annually	Complaints; Management Review Minutes	Supplier scorecards
8	**Bottling and Labeling**	Traceability	Unknown supplier lot used	Supplier labels are retained as well as BiosPacific label at receiving	Complaints	
		Traceability	Wrong product labeled	Line Clearance of labels/product is performed at receiving (Print and Post Purchase Order Receipt from SAGE) and verification after aliquoting (304.5.2)	Complaints	
		Fill volume/concentration	Wrong volume aliquoted	Verification is performed during the bottling process (304.5.2)	Complaints	
8	**Storage and Preservation**	Preservation of product	Temperature excursion resulting in loss of product	Remote site monitoring. Supplier: Senscoscientific	Thermometers are calibrated annually. Senscoscientific-Supplier performance is maintained.	
8	**Shipping, Logistics, and Transportation**	Shipping and packing	Wrong product, lot, or quantity shipped	Secondary person verifies each shipment	SOP	